REMARKS / ARGUMENTS

This Amendment is submitted in full response to the Office Action dated February 22, 2007, wherein claims 1-3, 5-7, 9-11, and 13-19 have been withdrawn from consideration as being drawn to a non-elected invention; claims 4 and 12 stand rejected under 35 U.S.C. §112, second paragraph; and claims 4, 8, 12, and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,368,051 to Dunn ("Dunn").

An appropriate Request for an Extension of Time and the corresponding fee are being filed concurrently herewith, and accordingly, Applicant respectfully requests reconsideration of this application in view of the foregoing amendments, the attached Declaration, and the following remarks.

To begin, Applicant has cancelled claims 4, 8, 12, and 20, thereby rendering the rejection of claims in the present Office Action moot. In addition, Applicant presents herein new independent claim 21, and new dependent claims 22-24 being dependent either directly or indirectly therefrom, which are all believed to be in condition for immediate allowance. Finally, Applicant has amended previously withdrawn claims 1-3, and seeks rejoinder of the same as discussed in more detail below.

A. Claim Rejections Under 35 U.S.C. §112, Second Paragraph.

Claims 4 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. As noted above, claims 4 and 12 have been cancelled herein, thus, the rejection under 35 U.S.C. §112, second paragraph, is deemed moot.

B. Obviousness Under 35 U.S.C. §103(a).

In view of the claim rejections under 35 U.S.C. §103 in the present Office Action, Applicant notes that Section 2142 of the Manual of Patent Examining Procedure ("MPEP") states that "[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." More recently, the Supreme Court, just this year, in KSR, Int'l Co. v. Teleflex, Inc., 127 S.Ct. 1727 (2007), reaffirmed the four (4) factors presented in Graham v. John Deere, Co., 383 U.S. 1 (1966), for a determination of obviousness under 35 U.S.C. §103(a), namely:

(1) determine the scope and content of the prior art,

(2) ***ascertain the differences between the prior art and the claims at issue,***

(3) resolve the level of ordinary skill in the art, and

(4) ***evaluate evidence of secondary considerations***.

Additionally, MPEP §2141(III) further provides that objective evidence or secondary considerations, such as unexpected results, must be considered in every case in which they are presented. In particular, "[a] greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." MPEP §716.02(a)(I) (quoting In re Corkill, 711 F.2d 1496 (Fed. Cir. 1985)). Furthermore, the presence of a property not possessed by the prior art, or the absence of a property which a claimed invention would have been expected to possess are both further evidence of non-obviousness. MPEP §716.02(a)(III)-(IV).

C. Claim Rejections Under 35 U.S.C. §103(a).

The above-referenced rejections of claims 4, 8, 12, and 20 are based exclusively on the reference of record to Dunn, the Applicant of the present Application. As noted above, claims 4, 8, 12, and 20 have been cancelled herein, and as such, the claim rejections under 35 U.S.C. §103 are deemed moot.

Applicant submits that newly presented claims 21-24, and

previously withdrawn claims 1-3, as amended herein, are not obvious in view of Dunn.

As an initial matter, Applicant submits that Dunn discloses a method of regenerating articular cartilage utilizing *large* dosages of purified growth hormone ("PGH"), namely, dosages in the range of 0.25 to 0.75 milligrams of PGH per kilogram of an individual's body weight. (Dunn, column 5, lines 46-49). Dunn, however, does not teach or suggest utilization of a *reduced* dosage of PGH as recited in newly presented claims 21-24, or in currently amended claims 1-3. Specifically, new independent claim 21, as presented herein, recites a single dosage of an anti-inflammatory composition comprising an amount of PGH of between about 0.025 to 0.249 milligrams per kilogram of a patient's body weight. In addition, dependent claims 22 and 24 further limit amount of PGH in a single dosage of the anti-inflammatory composition to between about 0.05 to 0.120 milligrams of PGH per kilogram of a patient's body weight.

In addition, attached hereto as Appendix I is the Declaration of Dr. Allan R. Dunn pursuant to 37 C.F.R. §1.132. Specifically, from about 1992 to 1993, the Applicant, Dr. Allan R. Dunn, personally conducted initial research directed towards

regeneration of cartilage via intra-articular injections of PGH into joints of patients at dosages in the range of 0.25 to 0.75 milligrams per kilogram of body weight, as disclosed in the cited reference to Dunn. (Appendix I ¶4). During this research, Applicant observed side effects, including elevated serum glucose levels and headaches, following intra-articular injections of PGH at the dosages disclosed in Dunn. (Appendix I ¶5).

From about 1999 to 2007, Applicant personally conducted research of the effects of reduced dosages of PGH, namely, dosages in the range of 0.025 to 0.249 milligrams of PGH per kilogram of body weight, as is recited in newly presented independent claim 21. (Appendix I ¶6). In the course of this research, Applicant observed that even a single intra-articular injection of PGH at the reduced dosage and the concentration range as recited in new independent claim 21 is effective for reducing and/or eliminating signs of inflammation, including pain, swelling, heat, and stiffness in the patients treated. (Appendix I ¶7). Furthermore, patients treated with intra-articular injections of PGH at the reduced dosages and the concentrations recited in newly presented claims 21-24 exhibited

no sign of the expected side effects, namely, elevated serum glucose levels and headaches. (Appendix I ¶9).

Furthermore, the Declaration of Dr. Allan R. Dunn sets forth a summary of the results obtained and observed for thirty-eight (38) patients treated with intra-articular injections of PGH at reduced dosages, i.e., dosages in a range of 0.025 to 0.249 milligrams of PGH per kilogram of body weight, wherein the PGH was administered at concentrations of about 5.0 to 6.0 milligrams per milliliter of buffer solution, as disclosed and claimed in the present Application. (Appendix I ¶¶13-24). Exhibit C of the Declaration of Dr. Allan R. Dunn sets forth with specificity the details of the treatment, as well as the pre-treatment and post-treatment evaluations and observations

Based upon Applicant's extensive research and expertise in the field of orthopedic surgery, Applicant submits that the results obtained by treating patients with intra-articular injections of PGH at the reduced dosages, and the concentrations recited in new claims 21-24 presented herein would **not** have been expected by one of ordinary skill in the art at the time of the invention. (Appendix I ¶25). Specifically, in view of the cited reference to Dunn, treatment with even a single dosage of

the anti-inflammatory composition as recited in newly presented independent claim 21, i.e., a reduced dosage of PGH, would have been expected to produce side effects, such as those observed following treatment with PGH at dosages taught by the cited reference to Dunn, for example, elevated serum glucose levels and headaches. In addition, treatment with a reduced dosage of PGH, as recited in newly presented independent claim 21, would not have been expected to exhibit anti-inflammatory or analgesic properties, based upon the reference to Dunn. Thus, the presence of unexpected anti-inflammatory and pain-reducing properties, combined with the absence of expected side effects, such as elevated serum glucose levels and headaches, following treatment with the composition recited in claims 21-24 is evidence that the composition recited in newly presented claims 21-24 would not have been obvious to one of ordinary skill in the art at the time of the invention in accordance with MPEP §716.02(a).

Accordingly, for at least the above reasons, including the objective evidence or secondary considerations discussed in detail herein, newly presented independent claim 21, and new dependent claims 22-24 depending therefrom, are believed to be

in condition for immediate allowance.

D. Rejoinder Under MPEP §821.04(b).

On January 4, 2007, Applicant elected to prosecute those claims which the Examiner categorized as Group II drawn to an anti-inflammatory composition comprising a growth hormone. Furthermore, the Office Action states that in order to retain the right to rejoinder, the process claims must be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims.

Accordingly, and in order to retain the right to rejoinder, previously withdrawn claims 1-3 have been amended herein to include the limitations of the single dosage of anti-inflammatory composition, i.e., the product, recited in newly presented independent claim 21 which, as noted above, is believed to be in condition for immediate allowance. Therefore, previously withdrawn claims 1-3, as amended herein are also believed to be in condition for allowance, and rejoinder of previously withdrawn claims 1-3, as amended herein, is hereby respectfully requested.

E. Inventorship.

As a final matter, the Office Action states that "[t]his application currently names joint inventors," however, Applicant respectfully directs the Examiner's attention to Applicant's signed Declaration dated March 5, 2004 and submitted to the PTO on April 22, 2004, which indicates Allan R. Dunn as the sole inventor of the present Application.

F. Conclusion.

Based on the foregoing remarks, the above amendments to the claims, and the Declaration of Dr. Alan R. Dunn, attached hereto as Appendix I, it is respectfully requested that this application be given full and favorable reconsideration. It is believed that upon doing so, this application will be deemed to be in condition for immediate allowance, which action is now respectfully requested.

In addition, a request for an appropriate extension of time is enclosed herewith along with the corresponding PTO fee. In the event that any additional fee may be required by the filing of this paper, the Commissioner is hereby authorized to charge any fees and/or credits to our **Deposit Account No. 13-1227.**

Respectfully Submitted,

MALLOY & MALLOY, P.A.
Attorneys for Applicant
2800 S.W. 3rd Avenue
Historic Coral Way
Miami, Florida 33129
(305)858-8000

By: _____
Jennie S. Malloy
Reg. No. 37,670

Date: 8/22/2007

APPENDIX I